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**Sterile single-use intravascular  
introducers, dilators and guidewires**

*Introduceurs, dilatateurs et guides intravasculaires stériles non  
réutilisables*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword — Supplementary information](#).

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition ~~is a technical revision of the first edition (ISO 11070:1998), which has been technically revised.~~ ~~and replaces the first edition (ISO 11070:1998), which has been technically revised.~~

## Introduction

The purpose of this International Standard is to

- update requirements and test methods to support the function of the guidewire, and
- update size designation.

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# Sterile single-use intravascular introducers, dilators and guidewires

## 1 Scope

This International Standard specifies requirements for introducer needles, introducer catheters, sheath introducers, guidewires, and dilators supplied in the sterile condition, and intended for single use in conjunction with intravascular catheters specified in ISO 10555-1.

NOTE Guidance on materials and design of accessory devices is given in [Annex A](#).

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-1<sup>1)</sup>, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2<sup>2)</sup>, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Schematic examples of the devices covered by this International Standard, with examples of terminology, are given for information in [Figure 1](#), [Figure 2](#), [Figure 3](#), and [Figure 4](#).

### 3.1

#### **coil (of a guidewire)**

helically wound wire

### 3.2

#### **core wire (of a guidewire)**

wire used to achieve stiffness of the *guidewire* (3.6)

### 3.3

#### **dilator**

flexible, tubular device used for dilating the percutaneous opening into a blood vessel

1) Upon its publication, ISO 80369-7 will replace ISO 594-1:1986.

2) Upon its publication, ISO 80369-7 will replace ISO 594-2:1998.

**3.4**  
**distal end**  
**patient end**

end of the device, which is inserted into the patient

**3.5**  
**effective length**

length of the device that can be inserted into the body

**3.6**  
**guidewire**

flexible device over which a catheter or *dilator* (3.3) is passed to assist in the insertion and location of the catheter or dilator into a blood vessel

Note 1 to entry: Examples of guidewire types are shown in [Figure 3](#).

**3.7**  
**hub**

connector(s) at the proximal end of the intravascular catheter introducer, which can either be integral with the introducer or be capable of being securely fitted to the proximal end of the introducer

**3.8**  
**introducer catheter**

short, flexible tube which is introduced into a blood vessel, typically over an introducer needle, and through which a catheter or guidewire can be introduced after removal of the introducer needle

**3.9**  
**intravascular catheter introducer**

device designed to be used in conjunction with an intravascular catheter to facilitate introduction into the vascular system

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**3.10**  
**introducer needle**

pointed, rigid tube through which a *guidewire* (3.6) or catheter can be introduced into a blood vessel

**3.11**  
**proximal end**  
**free end**

end of the device opposite the *distal end* (3.4)

**3.12**  
**safety wire (of a guidewire)**

additional wire used to minimize the possibility of detachment of the tip

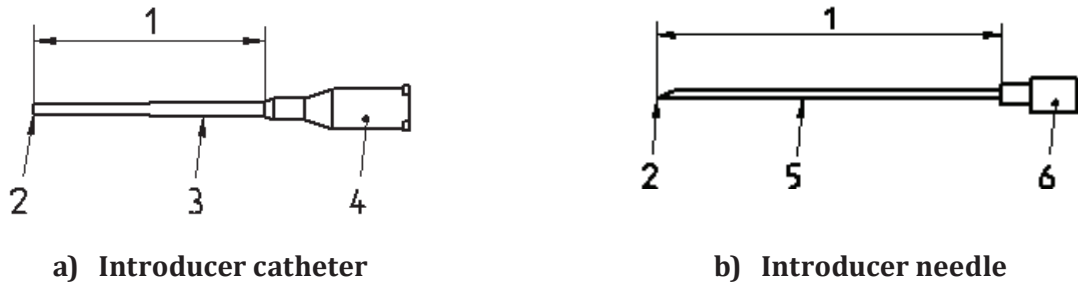
**3.13**  
**sheath introducer**

flexible tube which is introduced into a blood vessel, typically over a *dilator* (3.3), and through which a guidewire or catheter can be introduced after removal of the dilator

**3.14**  
**tip**

extremity of the *distal end* (3.4) of the device

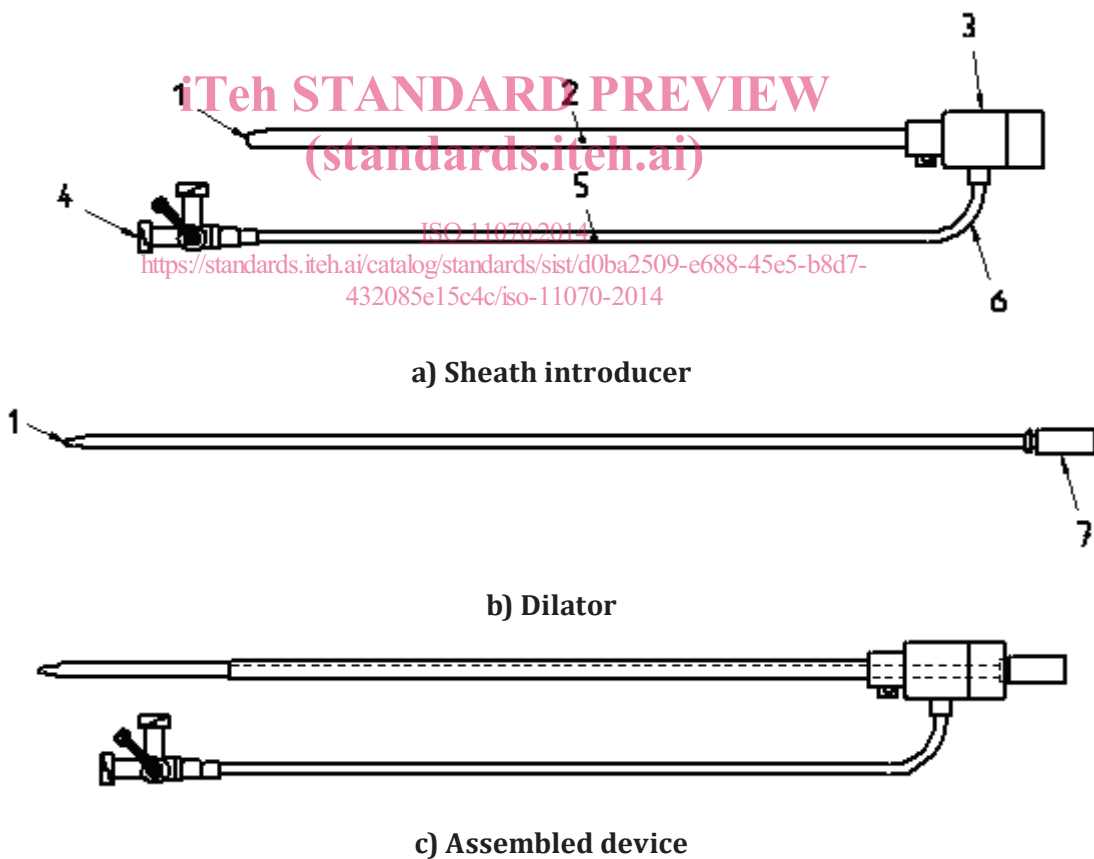




**Key**

- 1 effective length
- 2 distal end
- 3 catheter
- 4 catheter hub (optional)
- 5 introducer needle tube
- 6 needle hub

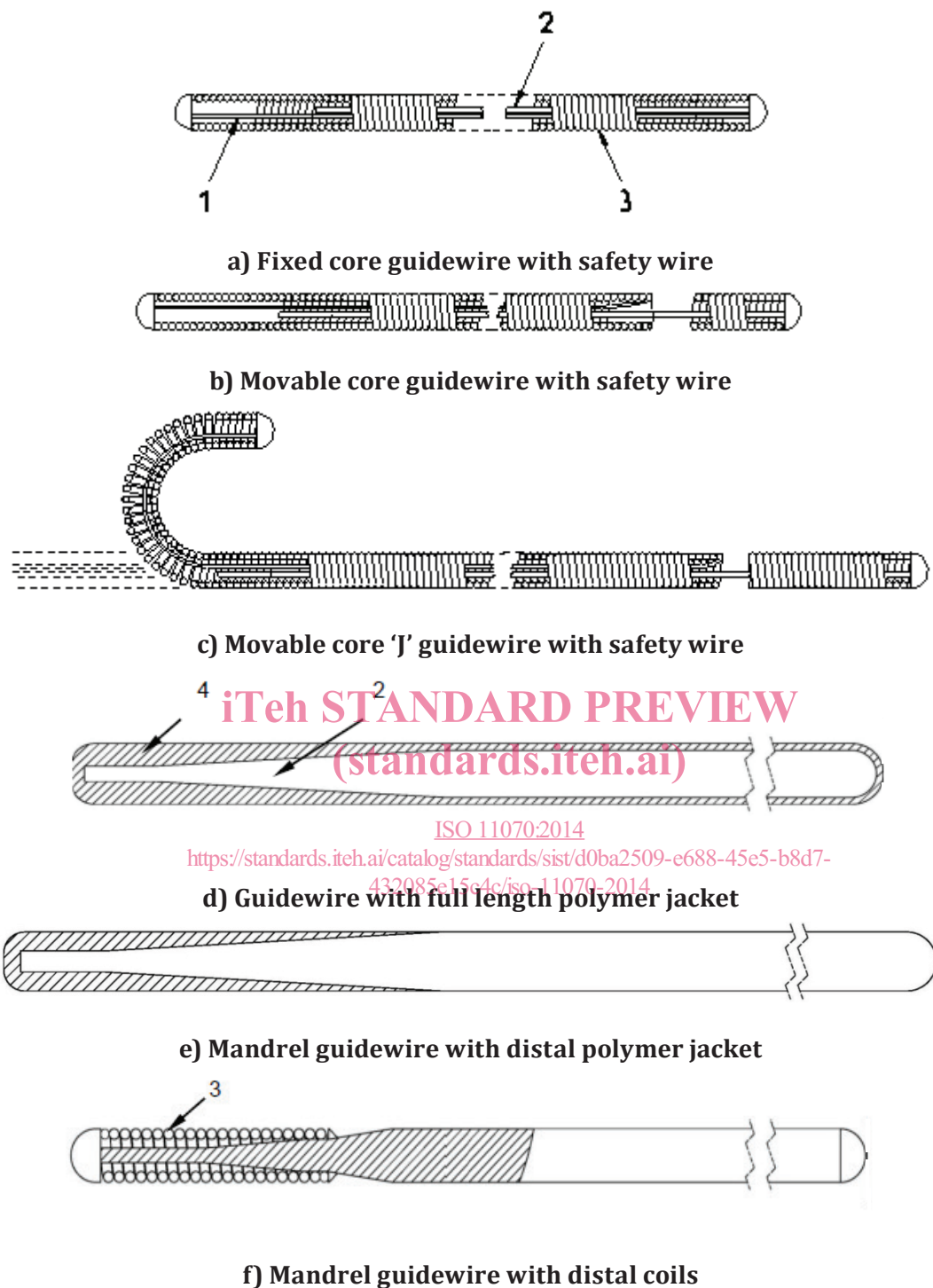
**Figure 1 — Example of an introducer catheter and an introducer needle**



**Key**

- 1 distal end
- 2 sheath
- 3 haemostasis valve (optional)
- 4 stopcock with Luer fitting
- 5 sidearm
- 6 sidearm connection (optional)
- 7 hub

**Figure 2 — Example of a sheath introducer and a dilator**



**Key**

- 1 safety wire
- 2 core wire
- 3 spring coil
- 4 polymer jacket

**Figure 3 — Examples of guidewires**

## 4 General requirements

### 4.1 Sterilization

The device shall have been sterilized by a validated method, and shall comply with 4.2 to 4.4 in the sterile condition.

NOTE See applicable part(s) of ISO 17665, ISO 11135, and ISO 11137 for appropriate methods of sterilization.

### 4.2 Biocompatibility

The device shall be free from biological hazard in accordance with appropriate testing under ISO 10993-1.

### 4.3 Surface

When examined by normal or corrected-to-normal vision with minimum 2,5x magnification, the external surface of the effective length of the device shall appear free from extraneous matter.

The external surface of the effective length of the device, including the distal end, shall be free from process and surface defects, which could cause trauma to vessels during use.

If the intravascular catheter introducer is lubricated, the lubricant shall not be visible as drops of fluid on the external surface of the effective length of the device when the device is examined under normal or corrected-to-normal vision.

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### 4.4 Corrosion resistance

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When tested in accordance with the method given in Annex B, if metallic components of the device show visible signs of corrosion that can affect functional performance, the level of corrosion shall be evaluated with respect to intended use and risk assessment.

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### 4.5 Radio-detectability

Parts of the device shall be radio-detectable if required as determined by the risk assessment.

Compliance should be demonstrated by an appropriate test method, such as ASTM F640-12 or DIN 13273-7.

### 4.6 Information to be supplied by the manufacturer

The manufacturer shall supply at least the information listed in a) to i). All dimensions given shall be expressed in SI units of measurement.

Units of other measurement systems can additionally be used.

Where appropriate, ISO 15223-1 should be used.

The following are the descriptions of the device:

- a) name or trade name and address of the manufacturer;
- b) batch code, preceded by the word LOT, or the serial number or the appropriate symbol;
- c) expiry date or use-by date expressed according to ISO 8601;
- d) any special storage and/or handling conditions;
- e) the word STERILE or the appropriate symbol;
- f) method of sterilization;

- g) an indication that the device is for single use or the appropriate symbol;
- h) any known incompatibilities with substances likely to be used with the device;
- i) instructions for use and warnings, as appropriate.

## 5 Additional requirements for introducer needles

### 5.1 General

The introducer needle shall comply with [Clause 4](#).

### 5.2 Size designation

The nominal size of the introducer needle shall be designated by the outside diameter, inside diameter, and the effective length as shown in [Table 1](#).

**Table 1 — Designation of nominal size of introducer needles and introducer catheters**

Dimensions in millimetres

Device diameter	Outside diameter rounded up to nearest	Inside diameter rounded down to nearest	Effective length rounded to nearest
≥0,6	0,1	0,1	1,0
<0,6	0,05	0,05	1,0

### 5.3 Needle point

When examined under 2,5x magnification, the needle point shall appear sharp and free from feather edges, burrs, and hooks (see ISO 7864).

### 5.4 Hub

#### 5.4.1 Conical fitting

If a hub is provided, the hub shall have a female 6 % (Luer) taper conical fitting complying with ISO 594-1 and/or ISO 594-2.

NOTE Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.

#### 5.4.2 Strength of union of needle tube and needle hub

When tested by the method given in [Annex I](#), the union of the needle tube and the needle hub shall not be loosened by a force of 10 N for needles of nominal outside diameter of less than 0,6 mm or of 20 N for needles of nominal outside diameter of 0,6 mm or greater.

### 5.5 Information to be supplied by the manufacturer

The manufacturer shall give the nominal size of the introducer needle as designated in [5.2](#).

## 6 Additional requirements for introducer catheters

### 6.1 General

The introducer catheter shall comply with [Clause 4](#).